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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/756,283	01/09/2001	Yuti Chernajovsky	0623.1000000/LLB/PAJ	5963

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EXAMINER
ANDRES, JANET L

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 07/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.	Applicant(s)	
09/756,283	CHERNAJOVSKY ET AL.	
Examiner	**Art Unit**	
Janet L. Andres	1646	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 10 June 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: *34-44*.

   Claim(s) objected to: *28 and 29*.

   Claim(s) rejected: *27, 30-33*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

Continuation of 3. Applicant's reply has overcome the following rejection(s): The rejection of claim 25 under 35 U.S.C. 112, second paragraph, is overcome by Applicant's amendment.

Continuation of 5. does NOT place the application in condition for allowance because: Claims 27 and 30-33 would remain rejected under 35 U.S.C. 112, first paragraph, as lacking enablement commensurate in scope with the claims. Applicant's amendment is not sufficient to overcome this rejection because the claims encompass all "anti-inflammatory cytokines". As was stated in the office action of paper no. 17, the art teaches that cytokines described as "anti-inflammatory" can have pro-inflammatory effects. Thus the mere designation of a cytokine as "anti-inflammatory" is not sufficeint to indicate that it will act as an anti-inflammatory agent and limiting the claim to molecules so designated is not sufficeint to limit it to those agents which are enabled for treatment of inflammation by the art. Claims 28 and 29 would be objected to as depending from a rejected base claim but would be allowable as independent claims, since there is sufficient guidance in the prior art for one of skill to identify interferons and interleukins that could be used to treat inflammation.

Claims 27 and 30-33 would remain rejected under 35 U.S.C. 103(a) as unpatentable over WO 91/08291. As was stated on pp. 2-3 of the office action of paper no. 17, these claims are unpatentable over WO 91/08291 because they encompass methods using TGF-beta molecules complexed with the latency-associated peptide of other TGF-beta molecules. Applicant's arguments with respect to other cytokines are not therefore not pertinent. Applicant argues with respect to TGF-beta molecules that WO 91/08291 does not teach such molecules. Applicant further argues that the reference discloses that at most it would be "obvious to try" such combinations. Applicant's arguments have been fully considered but have not been found to be persuasive. In considering the disclosure of a reference, it is proper to take into account not only specific teaching of the reference but also the inferences which one skilled in the art would be reasonably be expected to draw therefrom (In re Preda, 401 F.2d 825, 159 USPQ 342, 344 (CCPA 1968). WO 91/08291 explicitly teaches "the LAP is used in combination with a mature TGF-beta, whether hetrogeneous or homogeneous with the LAP. For example, a LAP from TGF-beta1 can be employed with mature TGF-beta1, TGF-beta2, or TGF-beta3" (p. 24, lines 29-30). Thus one of ordianry skill in the art would expect to be able to use LAPs with heterologous TGFs-beta. WO 91/08291 teaches that this approach would be successful. WO 91/08291 does not explicitly state that such LAPs may be directly fused with heterlogous TGFs-beta; it teaches that they may be administered as mixtures (p. 24, lines 31-32). However, in Figure 1, it is shown that TGF-beta is produced as a fusion product between mature TGF-beta and LAP. That complex is latent. Thius, since LAPs may be administered with heterologous TGFs-beta to produce latency, and a fusion product between TGF-beta and a homologous LAP is latent, one of ordianry skill would expect a fusion product between LAP and a heterogous TGF-beta to be latent.

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